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10/676,170	10/02/2003	Ross J. Hamel	SYNT-0108	6800
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WOODCOCK WASHBURN LLP			MAI, HAO D	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,170	<b>Applicant(s)</b> HAMEL, ROSS J.
	<b>Examiner</b> HAO D. MAI	<b>Art Unit</b> 3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 February 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4,7,9-17,19,21,23,25-36,40,41,44-50 and 52-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,7,9-17,19,21,23,25-36,40,41,44-50 and 52-67 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on 02/04/2009 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/12/2008 has been entered.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 52-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 52 recites the limitation "the hole" (lines 16 and 17), which lack sufficient antecedent basis. Such limitation should be corrected to be "the through-hole".

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1, 4-7, 9-17, 19, 21, 23, 25-30, 60-63, and 66-67, are rejected under 35 U.S.C. 102(b) as being anticipated by Koteles et al. (5,938,592).**

Regarding claim 1, Koteles et al. disclose surgical retractor (Fig. 2) comprising: a handle 22/34 having a longitudinal axis, proximal and distal ends, and a longitudinally elongated outer surface that is capable of being held by an operator; a first coupling mechanism 32 coupled to the proximal end of the handle; and a blade member 46 having proximal and distal ends. The coupling mechanism comprising a knob 42 having a bore, wherein at least a portion of the knob is disposed within the handle, and wherein the knob is rotatable about the longitudinal axis of the handle. The blade member 46 comprises a coupling element (shaft 24) being configured and dimensioned to be received in the bore of the knob; wherein rotation of the knob in a first direction causes shaft 24 to advance into the bore of the knob. As to the newly added limitation to claim 1, note that when the coupling element 24 is not received in the bore of the knob, the blade member is inherently detached from the handle.

As to claim 4-6, the coupling element 24 is a shaft having outer threads 44 to mate with the inner threads of the knob's bore; and the handle is shown to have an opening to receive knob 42. As to claims 7 and 9, Figure 7A shows a retractor blade having an opening (between extension 98, 100) at the distal end of the blade that is configured and dimensioned to be capable of allowing a surgical tool or an orthopedic to pass there through. As to claims 10-13, the blade has a structure that is capable of stabilizing itself against bone; and Figs. 7A-7C show the blade having a hook-shape with a C-shape and/or an L-shape.

As to claim 14, note the either of the second coupling 32 or the pivot clamp 54 can be a second coupling mechanism locating on the handle capable of coupling a second surgical instrument to the handle. As to claims 15-17, the second surgical instrument and any limitations

thereof are not given patentable because the second surgical instrument is only inferentially claimed.

As to claims 19, 21, and 23-27, Koteles et al. disclose a second coupling mechanism 50 comprising a coupling member (snap connection 58) contacting a second member (pivot clamp 54), wherein the coupling member 58 and the second member 54 are operatively associated to fix a second surgical instrument (rake 52) with respect to the handle. The coupling member/snap connection 58 is telescopically received within the handle and comprises a recess (formed by hook 64) capable of receiving a portion of rake 52 (Fig. 2). As to claims 28-29, Koteles et al. disclose another surgical instrument such as one of the retractor blades shown in Figs. 7A-8B having a coupling element (shaft 104) that is configured and dimensioned to connect interchangeably with the first coupling mechanism. As to claim 30, note the second handle (connector hub 70) being transverse to the longitudinal axis.

As to claims 60-63, note that the longitudinal axis extends through the first coupling mechanism 32 while the second coupling mechanism 50 is spaced from the longitudinal axis of the handle.

Regarding claims 66-67, Koteles et al. disclose all the elements as claimed as detailed above.

**6. Claims 52-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Furnish et al. (6,254,535).**

Regarding claim 52, Furnish et al. disclose a retractor 10 comprising: a handle 76/78/72 elongate along a longitudinal axis, the handle having a proximal end (towards 72), a distal end (towards 76), and an opening 73 (Fig. 1). The retractor further comprises a first coupling mechanism 74 coupled to the proximal end of the handle, wherein the first coupling mechanism is rotatable about the longitudinal axis of the handle (Fig. 1). The retractor further comprises a

second coupling mechanism comprising shaft 50 (best seen in Figure 5) disposed on a backside of the handle proximate the proximal end of the handle. The second coupling mechanism 50 having a through-hole (bore 58) and at least a portion of the through-hole is axially moveable within the opening 73 of the handle; wherein the through-hole/bore 58 is sized and configured to be capable of receiving a surgical instrument (e.g. shaft 80 or stabilizer 44). The retractor further comprises a blade 20 (best seen in Figs. 1 and 6) having a proximal end and a distal end. The blade member comprises a coupling element (slide segment 22) connecting with the first coupling mechanism 74. Note that the coupling element 22 of the blade member 20 is configured and dimensioned to connect with the first coupling mechanism 74 (Fig. 1) regardless of whether the surgical instrument (shaft 80 or stabilizer 44) is received in the through hole/bore 58 of the second coupling mechanism 50; and the surgical instrument 80 or 44 can be received in the hole of the second coupling mechanism 50 regardless of whether the blade member 20 is connected with the first coupling mechanism.

As to claim 53, the surgical instrument and any structures thereof are not given any patentable weight since the surgical instrument was only inferentially claimed. As to claims 54, the second coupling mechanism is a clamping member (shaft 50) telescopically received within the handle at handle's opening 73 (best seen in Fig. 1). As to claims 55-58, note that there is a second member between the clamping member 50 and the handle's portion 72, so that the clamping member 50 is not in direct contact with the handle. The clamping member 50 and the second member are operatively associated with each other to fix the surgical instrument with respect to the handle. As to claim 59, the clamping member 50 comprises an inner surface that defines a portion of the through-hole (bore 58), the surface capable of receiving a portion of the surgical instrument, e.g. shaft 80 or stabilizer 44.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 31-36, 40-41, 44-47, and 64-65, are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg (5,558,622) in view of Koteles et al.**

Greenberg discloses a method for treating a bone that includes providing the surgical retractor, making an incision in the soft tissue and elevating the tissue off the bone (Fig. 17, S, SI, OI and M), passing a portion of the blade through the incision and retracting the tissue (Fig. 17, OI), circumventing at least part of the bone with a portion of the blade and stabilizing a portion of the blade on the bone (Fig. 17, #'s 58, 59, and M), and performing a surgical procedure on the bone (Fig. 17, D and P). Additionally, part of the procedure involves using a surgical tool (D) to pass an orthopedic implant (P) through the cavity (SI) and the aperture of the blade (Fig. 17, #60). The surgical instrument can be a drill (and therefore a burr) (Column 6, lines 22-27) inserted through a drill guide or cannula (Column 2, lines 14-19). The implant secured to the bone can be a bone fastener or a screw (Column 6, lines 22-27) and used in an orthognathic procedure to fixate a fracture (Claim 32) on a bone segment (mandible) that comprises a condylar neck and a ramus.

Greenberg however fails to disclose the retractor as claimed. Koteles et al. disclose the claimed retractor as detailed above with respect to claim 1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Greenberg's retractor with the retractor of Koteles et al. as a suitable alternative retractor while still obtaining

the same and or predictable results. Note that when the coupling element (shaft 24) is not received in the bore of knob 42, the blade member 46 is inherently detached from the handle.

9. **Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg in view of Koteles et al., as applied to claim 44 above, and further in view of Swaniger (US 4,769,011).**

Greenberg in combination with Koteles, disclose the claimed methods as described above, with the exception of using a grafting procedure. Swaniger discloses methods for mandibular surgery that are well known in the art including a grafting procedure (Column 1, lines 21-24), using a biocompatible bone filler material (Column 1, lines 30-38), and the use of a syringe to implant the bone filler material (Column 2, lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform a grafting procedure as taught by Swaniger in order to augment the alveolar ridge.

***Response to Arguments***

10. Applicant's arguments with respect to Koteles et al. are not persuasive. Note that the structures 22 and 34 together can form a handle as claimed, wherein the a portion of knob 42 is disposed within handle 22/34.

Applicant's amendments to the claims have overcome Scirica and Wells; and the rejections under Scirica and Wells thus have been withdrawn.

Applicant's arguments regarding Furnish et al. are not persuasive. The examiner maintains that the structure 76/78/72 together form a handle as claimed according to claim 52. The handle 76/78/72 is elongate along a longitudinal axis, having proximal and distal ends, and an opening 73; wherein the first coupling mechanism 74 is rotatable along the longitudinal axis (Fig. 1).

***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hao D Mai/  
Examiner, Art Unit 3732

/Cris L. Rodriguez/  
Supervisory Patent Examiner, Art Unit 3732